IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BRECKENRIDGE PHARMACEUTICAL, INC.,	)	
Plaintiff,	)	
v.	)	Civil Action No. 07-CV-11114(RWS)
MIDLAND HEALTHCARE, LLC,	)	
Defendant.	)	JURY TRIAL DEMANDED

REPLY MEMORANDUM OF LAW IN SUPPORT OF THE MOTION OF BRECKENRIDGE PHARMACEUTICAL, INC. FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

Defendant Midland Healthcare, LLC ("Midland") attempts to resist summary judgment by relying entirely on a declaration by Mr. Raman Kapur, unsupported by any documents, to create the illusion that there are disputed issues of material fact. This effort fails completely. The averments in Mr. Kapur's Declaration are controverted by his own prior written statements and by the explicit language in the Agreement at issue. His bald assertions cannot be credited by the Court and will not support denial of the Motion, especially in the absence of supporting documentation that Midland would have been able to submit if his averments were true.

The underlying facts are contained in the Local Civil Rule 56.1 Statement of Undisputed Material Facts and the accompanying declarations filed by Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") in support of its Motion. Midland failed to controvert Breckenridge's Rule 56.1 Statement as required by Local Civil Rule 56.1(c), so the Court may accept Plaintiff's statement of facts as true for the purpose of this Motion, especially since, as explained below, Mr. Kapur's unsupported statements cannot be credited. *Nigro v. Dwyer*, F. Supp. 2d 229, 231 (S.D.N.Y. 2006) ("Defendant's failure to comply with Rule 56.1 permits the Court to deem the facts in plaintiffs' Rule 56.1 Statement uncontroverted").

ARGUMENT

I. THE MOTION FOR SUMMARY JUDGMENT SHOULD BE GRANTED BECAUSE MIDLAND'S UNCORROBORATED DECLARATION IS NOT SUFFICIENT TO RAISE A DISPUTED ISSUE OF MATERIAL FACT

As the party that was responsible for accomplishing the Milestones in the Agreement, and also for providing accurate monthly status reports to Breckenridge, Midland would be expected to have documentary evidence of the work it performed, and copies of reports it provided to Breckenridge. Breckenridge does not have the burden of proving a negative. But rather than submit copies of laboratory results, batch sheets, status reports, or any document to corroborate its

assertions, Midland tries to resist summary judgment entirely by relying on the declaration of Mr. Kapur.[1] Where a party would be expected to have supporting documents in its possession, this is not enough to defeat summary judgment – especially because, as explained below, the bald assertions of Mr. Kapur are contradicted by his own prior statements in emails to Breckenridge and by the Agreement itself. *Sterling Financial Services v. Franklin*, No. 06-3511, 2008 WL 60291, at *2 (2d Cir. Jan. 7, 2008) (summary order available at www.ca2.uscourts.gov (holding that a declaration was "properly credited no weight" because it "was conclusory with no original documentary corroboration") (emphasis added); *Slowiak v. Land O'Lakes, Inc.*, 987 F.2d 1293, 1295 (7th Cir. 1993) ("Self-serving affidavits without factual support in the record will not defeat a motion for summary judgment.") (citations omitted); *Rhone v. U.S.*, 2007 WL 3340836, at *9 (S.D.N.Y. Nov. 9, 2007) ("Courts have made clear, however, that a plaintiff's own self-serving statements are insufficient to raise a triable issue of fact.") (citations omitted); *Akinde v. Bronx-Lebanon Hosp. Center*, 2005 WL 2024891, at *7 (S.D.N.Y. Aug. 23, 2005) (granting defendant's summary judgment motion after finding that plaintiff's submissions in response "consist entirely of unsubstantiated assertions unaccompanied by any corroborating materials").

II. MR. KAPUR'S ASSERTIONS THAT MIDLAND ACCOMPLISHED THE MILESTONES ARE DISPROVED BY HIS OWN EMAILS AND BY THE WRITTEN PROVISIONS OF THE AGREEMENT

A. Midland Never Accomplished Milestone 2: Completion of Formulation Development (Due In Late May)

The first Milestone that represented performance under the Agreement was Milestone 2, "Completion of Formulation Development," to be accomplished by late May. (*See* Exh. 5.) As defined in the Agreement, "completion of formulation development" included "receipt by Breckenridge of acceptable comparative assay results for the pilot-scale batch, and successful

[1] Midland does include a document prepared by Mr. Kapur that contains a list of purported costs, but it does not contain dates, vendors, or any other specifics, and is not supported by invoices or any other original documents.

completion of analytical method validation, including impurities." (Exh. 1, section 1.7.) Both Mr. Lapila and Breckenridge's regulatory consultant, Mr. Falconer, have averred that they discovered in the September, 2007 site visit that "Midland had not produced a pilot-scale batch of the Product, had not produced comparative assay results, [and] had not completed analytical method validation." **(**Falconer Decl., ¶ 4; Lapila Decl., ¶ 13.)

Midland does not dispute any of the foregoing. Instead, Mr. Kapur asserts that Midland met this Milestone with a batch of the Product produced in India ("the pilot formulation that was developed in India"). (Kapur Decl., ¶ 10.) He also asserts that a stability study had been conducted with that batch. *Id.* Even if such a formulation batch was actually produced in India, Midland could not meet Milestone 2 of the Agreement based on this batch, for at least the following four reasons:

First, if Midland actually intended this "pilot-scale batch" in India to meet the requirements for completion of the formulation development, then it was contractually required to provide Breckenridge with the "comparative assay results for the pilot-scale batch, and successful completion of analytical method validation, including impurities" for that batch. (Agreement, section 1.7 (Exh. 1).) Milestone 2 thus expressly requires the delivery of documents to Breckenridge to confirm successful formulation development. Mr. Kapur recognized this, as he emailed to Mr. Lapila that his colleague Paul Sudhakar would provide the report for that batch to Rob Falconer. (*See* Exh. 7.)

But Midland did not provide any such information to Breckenridge, including the report referred to by Mr. Kapur in his October 9th email. (Lapila Supp. Decl., ¶ 5.) Mr. Kapur does not assert that it was provided, only that Breckenridge "understood" that a study had been performed on a batch in India. (Kapur Decl., ¶ 10.) Since documentary evidence of providing this report, whether email or hard copy, would be in Midland's possession, Midland's failure to

submit any such documentation must be seen as confirmation that it was not in fact provided. Because these required reports were never provided to Breckenridge, Midland never met Milestone 2 – the first agreed-upon Milestone after execution of the Agreement itself.

Second, Midland is a Kansas limited liability company with its facilities located in Kansas City.[2] If any of the work required by the Agreement was done in India on behalf of Midland, it was necessarily performed by another entity as subcontractor (whether or not an affiliate of Midland). But section 4.1 on the Agreement specifically restricts both Midland and Breckenridge from contracting with "any third party" to "assist in the development" of the Product except with the "express written consent of the other party." (*See* Exh. 6 (pp. 7-8 of the Agreement, not previously submitted)). Section 4.2 provides that Midland may subcontract work with third parties, including any affiliates, "[u]pon the prior written consent of Breckenridge." *Id*. Midland did not request, and Breckenridge never provided, any such prior approval for Midland to have any of the work under the Agreement performed by any third party, whether in India or elsewhere. Lapila Supp. Decl., ¶ 7. (If any such written approval existed, assuredly Midland would have submitted this in support of its opposition to this motion.). Breckenridge requires such consent to ensure that any outsourced work – especially in India or China – meets applicable FDA regulations and its own stringent quality requirements. Thus, even assuming Midland possessed successful assay results and validated methods for its work in India, this work was not authorized and would not be acceptable for purposes of satisfying Milestone 2.

Third, Midland avers that Breckenridge was aware that "[t]he subject formulation had been developed prior to the Agreement [having been executed]." (Midland R. 56.1 counter-

[2] See paragraph 3 of the Complaint. Midland's Answer does not appear to address this paragraph.

statement of facts., ¶ 3.) The Milestones contemplate new work to be done for the benefit of Breckenridge, beginning with completion of formulation development 60 days later. (Exh. 5.) Obviously, this does not refer to unauthorized work already performed by an unknown company in India.

Fourth, it turned out that the reason this report was not provided to Breckenridge was that the batch in India was produced for a different pharmaceutical company. (Lapila Supp. Decl. ¶ 6.) Accordingly, there was no development batch prepared in India for Breckenridge pursuant to the Agreement, and the information about that batch required by section 1.7 (even if it had actually been provided to Breckenridge) could not have satisfied the Agreement. Thus Milestone 2 – completion of formulation development – was never accomplished by Midland.

B. Midland Never Accomplished Milestone 3: Production Of The "Scale-Up" Or "Exhibit" Batch For Use In The Three-Month Accelerated Stability Study (Batch Production Due In Late July)

The Agreement defines Milestone 3 as "Completion of Scale-Up" – that is, production of a "stability batch" which would be used for the three-month stability testing required for Milestone 4[3] and which would be referenced in the submission to FDA. (Exh. 5.) Thus, the Agreement provides that this was due 180 days after execution, or in late July, to allow three months for the stability test, results of which were due in early November. *Id.* Unlike Milestone 2, Mr. Kapur refrains from asserting any specifics respecting how, when or where Midland purportedly met Milestone 3. Instead, he states only that Midland was "paid fifty-thousand ($50,000) dollars for having met Milestone 3," and that Midland "had been partially paid for the work done between Milestones . . . III and IV." Kapur Decl., ¶¶ 9-10. These statements are directly contradicted by his own email of October 9, 2007. (Exh. 7.)

[3] This was also referred to as the "exhibit batch." See the explanation of stability on a pilot-scale as opposed the accelerated three-month stability study in Lapila Supp. Decl., ¶ 2; *see also* Kapur Decl., ¶ 10 (referencing two different stability studies).

The first of this email string is Mr. Lapila's email of September 26, 2007 (previously submitted as Exhibit 2) in which he informed Mr. Kapur that Breckenridge was "very disappointed" to learn on its site visit that the Product was not on schedule as Midland had previously represented. Mr. Lapila then followed up with an email on October 8, 2007, requesting an update (after not having received any response from Midland). (Exh. 7.) In response, Mr. Kapur first informed Mr. Lapila of stability data from a "development batch done in India," and represented that his colleague Paul Sudhakar would provide the "Report for that batch" to Rob Falconer. *Id.* (As discussed above, however, this report was never provided to Breckenridge.)

Mr. Kapur then added that Mr. Sudhakar "has to make some revisions to the schedule for the production of the stability batch which he will forward to Breckenridge before the end of the week." *Id.* (emphasis added). Finally, he closed this email with "The delay is much regretted – I do not know what to say." *Id.* Thus, according to Mr. Kapur's own contemporary statement in his October 9, 2007, email, Milestone 3 – production of a "scale-up" batch that would be used for the stability test needed for Milestone 4 – had not yet been met, and in fact Midland had not even provided the "revised schedule" for the production of this batch. *Id.*

C. Midland Never Accomplished Milestone 4: Satisfactory Results From The Three-Month Stability Study (Results Due In Early November, So Due To Begin In Early August)

Milestone 4 is the "Receipt by Breckenridge of satisfactory 3-month accelerated stability results for ANDA Exhibit Batch" at "280 days from Project Commencement Date." (Exh. 5.) Thus, Breckenridge was to receive these results 40 weeks after project commencement on January 26, 2007 – that is, by November 2, 2007. Mr. Kapur does not assert that Midland met this Milestone, but does aver, as noted above, that Midland was "had been partially paid for the work done between Milestones . . . III and IV." (Kapur Decl., ¶ 10.) But Mr. Kapur himself

acknowledged that the "exhibit batch," required before the three-month stability study could even begin, had not yet been produced or even scheduled as of October 9, 2007. (Exh. 7.)

II. MR. KAPUR'S OTHER ASSERTIONS ARE ALSO DISPROVED BY HIS OWN EMAILS, THE AGREEMENT, OR OTHER EVIDENCE

A. Mr. Kapur's Assertion That Receipt Of Payments From Breckenridge Confirms That Midland Accomplished The Milestones Is Contradicted By The Agreement

Mr. Kapur asserts in paragraph 9 of his Declaration that "Breckenridge's claims that the Milestones were not met is contravened by the fact that they paid for the very Milestones that are alleged not to have been met." However, as noted above, the Agreement provided that Breckenridge was to pay Midland a fixed amount each month, in anticipation of its meeting the Milestones. (Exh. 5.) Only after making a number of such payments did Breckenridge discover that Midland had in fact not met any of the Milestones after executing the Agreement, at which point Breckenridge demanded the return of its money. (Lapila Supp. Decl., ¶ 13; Lapila Decl., ¶ 17; Exh. 3.)

B. Mr. Kapur's Assertion That He Never Admitted In His Emails That Midland Had Not Met Its Obligations Under The Agreement Is Contradicted By His Own Words In His Emails

Mr. Kapur asserts in paragraph 7 of his Declaration that "in the exchange of emails with Mr. Lapila" he did not "admit, either directly, or by implication . . . that Midland was in default of their obligations in the development of the subject product under the terms of the agreement." This statement is belied by the content of those emails. *See* the email exchange submitted previously as Exhibit 3; these emails from Mr. Kapur can only be understood as (at least) implicit acknowledgement of Midland's failure to meet the Milestones.

In addition, in response this denial by Mr. Kapur of his own prior statements, Breckenridge has submitted Exhibit 7, containing the October 9, 2007, email from Mr. Kapur referenced above. In this email he explicitly stated that the exhibit batch for Milestone 3 (due in

late July, 2007) had not yet been scheduled (much less produced), and that "[t]he delay is much regretted – I do not know what to say." It is hard to imagine a more explicit acknowledgement that Midland had not met its contractual obligations to accomplish the Milestones by the dates defined in the Agreement.

C. Mr. Kapur's Unsupported Assertion That Midland Kept Breckenridge Informed Of The Progress Of The Development As Required Cannot Be Credited

In paragraph 6 of his Declaration, Mr. Kapur asserts that "Midland has kept Breckenridge informed of the progress of the development of the product as required." But the Agreement specifically requires Midland to provide "monthly reports describing the progress of the development of the Product." Exh. 1, section 2.3. This is yet another category of documents that, if they existed, Midland would be expected to submit in opposition to summary judgment. It did not. Moreover, it is clear from the email exchanges following the September 14, 2007 site visit that Midland had not kept Breckenridge informed, but rather had misrepresented their progress on the development of the Product. (*See* Exh. 2, 3, and 7.)

D. Mr. Kapur's Assertion That Breckenridge Was Required To Provide Midland With A 60-Day Cure Period Is Contradicted By The Agreement Because Midland Could Not Provide The Results Of A Three-Month Stability Test In 60 Days

Mr. Kapur asserts in paragraph 11 of his Declaration, "The Agreement required that Breckenridge provide a sixty day 'cure' period in order to allow Midland the opportunity to remedy any alleged breach. . . . Breckenridge never provided the required 60 day notice and never allowed Midland the opportunity to cure any alleged breach under the Agreement."

Section 7.2(b) of the Agreement, referenced by Mr. Kapur, provides:

> Breckenridge may terminate this Agreement for Midland's material breach of its obligations hereunder; material breach is defined to include (i) failure to accomplish certain Milestones in accordance with Exhibit B, (ii) provide reports in accordance with section 2.3 . . . at any time by giving at least sixty (60) days prior written notice of termination to Midland, so long as Midland fails to remedy the breach to reasonable satisfaction of

> Breckenridge prior to the expiration of the sixty (60) day notice period **provided the breach is capable of being cured within the 60 day period**.

Exh. 1, section 7.2(b) (emphasis added). As explained above, Milestone 4 required Midland to provide Breckenridge with the results of a three-month stability study by November 2, 2007. As of October 9, 2007, the exhibit batch on which this study would be performed had not yet been produced (or even scheduled).

Thus, Midland's failure to satisfy Milestone 2 on time led to its subsequent breach of its obligation to provide the Milestone 4 three-month stability test results by November 2, 2007. This breach was not "capable of being cured within the 60 day period." No matter how long Midland might have been given – 60 days or 60 years – it is not possible to "cure" a missed deadline by waiting even longer. Moreover, Midland had not produced the exhibit batch and begun the stability test as of the time Breckenridge sent the termination letter on November 30, 2007. Mr. Kapur does not aver otherwise, but states that "it was understood that . . . the accelerated stability study for the ANDA, would be conducted on the exhibit batch . . . ." Even if "meeting" the November 2 deadline 60 days after the November 30 termination letter could be considered a "cure," Midland could not have performed a three-month stability study in the 60 day cure period.[4]

E. Mr. Kapur's Assertion That Action By The FDA Influenced Breckenridge's Decision Is Contradicted By The Later Date Of The FDA's Action

Mr. Kapur asserts in paragraph 8 of his Declaration that "Breckenridge, upon learning of the FDA had changed the subject product of the Agreement from an Rx product to a OTC (over-the-counter) product, sought any opportunity to exit the project and end the relationship with Midland." There simply is no basis for this statement. It is directly contradicted by information

[4] In spite of this, out of an excess of caution, Breckenridge did not file its motion for summary judgment until after 60 days had passed.

publicly available from the FDA, which shows that the conversion from a prescription product to over-the-counter occurred weeks after Breckenridge discovered that Midland had not met Milestone 2 or 3, and would not be able to meet Milestone 4 by the November 2 deadline.[5]

F. Mr. Kapur's Assertion That Midland Is Owed Some Of Its Costs In Spite Of Not Meeting Any Of The Milestones Is Not Supported By The Agreement

Mr. Kapur insists that section 7.2(b) of the Agreement requires Breckenridge to reimburse Midland for its costs incurred for "actual services rendered." However, as explained in Breckenridge's opening brief, after contracting to render specifically defined services to Breckenridge related to the development of the Product, Midland did not render any of these services, in spite of being paid $200,000. Midland has now confirmed this in its opposition papers. In paragraph 3 of Midland's Rule 56.1 counter-statement of facts, Midland states that "[t]he subject formulation had been developed prior to the Agreement and plaintiff had been informed that a stability study had been conducted in India . . . ." (Emphasis added.) In sum, Midland did some prior work in India, that it later refused to share with Breckenridge, and then after execution of the Agreement Midland collected monthly payments from Breckenridge while accomplishing not even the first subsequent Milestone, completion of formulation development. Midland should be required to return to Breckenridge the $200,000 that it collected under false pretences.

CONCLUSION

Based on the foregoing, Breckenridge respectfully requests that the Court grant it summary judgment on its claim against Midland.

[5] If necessary, Breckenridge will provide the information available from the FDA website in camera, as disclosure of the exact date of FDA action would disclose the identity of the Product which was the subject of the Agreement (which is being maintained as a trade secret).

Dated: New York, New York
March 10, 2008

/s/ C. Randolph Ross

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Plaintiff,	)	
v.	)	Civil Action No. 07-CV-11114(RWS)
MIDLAND HEALTHCARE, LLC,	)	
Defendant.	)	JURY TRIAL DEMANDED

SUPPLEMENTAL DECLARATION OF LARRY J. LAPILA
IN SUPPORT OF THE MOTION OF BRECKENRIDGE PHARMACEUTICAL, INC.
FOR SUMMARY JUDGMENT

I, LARRY J. LAPILA, declare as follows, as supplementation to my Declaration dated January 30, 2008 (which I incorporate herein by reference), and in response to the Declaration of Mr. Raman Kapur, dated February 26, 2008:

1. For the convenience of the Court, attached as Exhibit 5 is a separate copy of the "Milestones" portion of the ANDA Development, Manufacture, and Supply Agreement (the "Agreement") entered into by Breckenridge Pharmaceutical, Inc. ("Breckenridge ") and Midland Healthcare, LLC ("Midland") on January 26, 2008.

2. As a clarification of the many references to "stability" studies in the emails and other documents, as a matter of industry practice there are two separate stability studies that are typically performed in preparing an ANDA application to be submitted to the FDA. First, as I stated in paragraph 11 of my prior Declaration, "one of the standard steps required for formulation development of a pharmaceutical product is stability testing on product that has been produced pursuant to the formulation." This "proof of concept" stability testing is performed on

the pilot formulation or pilot batch that was to be produced as part of meeting Milestone 2. Second, there is then the accelerated three-month stability study performed on the exhibit batch to be submitted to the FDA, that is explicitly required as Milestone 4 of the Agreement (which was to be performed on the batch produced to meet Milestone 3).

3. As explained below, Mr. Kapur is mistaken when he asserts that the stability study conducted on the pilot formulation in India fulfilled the requirements of Milestone 2.

4. Milestone 2 (completion of formulation development) required "receipt by Breckenridge of acceptable comparative assay results for the pilot-scale batch, and successful completion of analytical method validation, including impurities." (Exh. 1, section 1.7.) After I learned in September, 2007, that Midland had not timely completed Milestone 2, I exchanged a number of emails with Mr. Kapur to request any updates. (This email and related reply emails are attached as Exhibit 7.) In his October 9 email, Mr. Kapur indicated that he understood the requirement for Midland to submit such information to Breckenridge, as he stated that his colleague, Mr. Paul Sudhakar, would provide this report to Rob Falconer, Breckenridge's regulatory consultant. (Exh. 7.)

5. However, to this day, this report was never provided to Mr. Falconer or to anyone else at Breckenridge. No stability data concerning the "pilot formulation batch" in India, nor any of the other information required by section 1.7 for completion of formulation development, was ever provided to Breckenridge. Midland thus did not satisfy Milestone 2.

6. Instead, Breckenridge was informed that the information concerning this "development batch" in India was proprietary to another pharmaceutical company and so could not be shared with Breckenridge, because it was performed by or for such other company.

7. Midland was required by section 4.1 and 4.2 of the Agreement to obtain the prior

written approval of Breckenridge for any such work performed by a subcontractor or affiliate of Midland. Attached as Exhibit 6 is a copy of pages 7-8 of the Agreement, which contain these sections. (These pages were not previously submitted.). No such consent was requested of, or provided by, Breckenridge.

8. Milestone 4 required that the results of the three-month accelerated stability study were to be provided to Breckenridge 280 days after commencement of the project, or by November 2, 2007. (Exh. 5.)

9. In order for the three-month stability study to be performed on time, Milestone 3 called for completion of scale-up by late July, 2007. (Exh. 5.) This "scale-up" includes the production of the stability or exhibit batch.

10. In his October 9 email, Mr. Kapur conceded that the project had been delayed (and apologized for that). (Exh. 7.) He also stated that the schedule for "the production of the stability batch" was being revised and would be provided to Breckenridge by the end of that week. *Id.* That is, the batch that was required for the three-month stability test had not yet been produced. In fact Breckenridge had not yet been provided a date for this production.

11. It was in this same email that Mr. Kapur first informed me that Midland had stability data from a pilot formulation batch done in India – as evidenced by my question in response to this email. (Exh. 7.) (As Mr. Kapur indicates in his declaration, this referred to the first stability study understood to be part of Milestone 2, not to the accelerated three-month stability study required for Milestone 4. Kapur Decl., ¶ 10.) As I stated above, Midland never requested and never received the consent of Breckenridge to have such work performed by another party, whether an affiliate of Midland or an unrelated third-party contractor, and moreover never provided Breckenridge with any such data.

12. While Midland may have been involved in the production of a formulation batch with another party in India, which Mr. Kapur now concedes was completed prior to execution of our Agreement, it never completed formulation development pursuant to and in furtherance of its Agreement with Breckenridge, and so never accomplished Milestone 2. Thus, Mr. Kapur's own statements support the conclusion that after the Agreement was executed, Midland never performed for Breckenridge any of the services for which it was paid pursuant to the Agreement.

13. As provided in the Milestones section of the Agreement (Exh. 5), Breckenridge made specified monthly payments to Midland. These payments were not made based on Midland having actually met the Milestones to earn those payments, but were rather made in a good-faith expectation that Midland would meet the Milestones as agreed. These payments were continued until September because Midland failed to apprise us of the true status of the project. Breckenridge did not discover the true state of affairs – that Midland had not performed any of the agreed-upon services – until the on-site audit in September, 2007 and promptly ceased payment at that time.

I declare under penalty of perjury, that the foregoing is true and correct.

Executed at New Berlin, Connecticut on March 12, 2008.

EXHIBIT B — ***Payments Upon Milestone Achievement and Royalties***

(1) MILESTONES:

In consideration for the successful completion of the Services by Midland, Breckenridge shall pay Midland a flat fee of [redacted] inclusive of all fees, costs, and expenses ("Development Fee"). The Development Fee shall be paid in monthly installments in the amount of [redacted] for [redacted] consecutive months beginning in the month of contract execution, with [redacted] upon ANDA filing and acceptance and [redacted] upon FDA approval (including tentative) of the ANDA. The continuation of monthly payments by Breckenridge shall be contingent only upon Midland successfully completing each of the Milestones, as set forth below, subject to amendment upon mutual agreement by the parties:

Milestone	TimeTables	Description	Individual Milestone Payment to Have Been Made to Midland	Cumulative Payments
1	Execution of Agreement	Project Commencement	[redacted]	[redacted]
2	120 days from Project Commencement Date	Completion of Formulation Development	[redacted]	[redacted]
3	180 days from Project Commencement Date	Completion of Scale-Up	[redacted]	[redacted]
4	280 days from Project Commencement Date	Receipt by Breckenridge of satisfactory 3-month accelerated stability results for ANDA Exhibit Batch	[redacted]	[redacted]
5	340 days from Project Commencement Date	ANDA Filing	[redacted] (Within 15 days of receipt of acceptance notice by FDA of the ANDA)	[redacted]
6	n/a	ANDA Approval	[redacted] (within 15 days of FDA approval or tentative approval of the ANDA)	[redacted]

protecting intellectual property and complying with regulatory requirements, which will be complete and accurate and will fully and properly reflect all work done and results achieved in the performance of its Services, including prompt signing and corroboration of laboratory notebooks and conception documents.

(b) Audit and Inspection. Upon reasonable prior notice by one party, the other party shall make open and available its facilities, employees, agents, and documentation related to its provision of Services and/or the manufacturing of the Product as well as other operations including sales and shipment records. No event later than seven (7) business days after receipt or submission, a party shall provide to the other party copies of all correspondences, deficiency letters, 483's, warning letters, responses, and other documents which concern or may concern the Product and/or a party's ability to provide services hereunder.

(c) Recalls. If any Product is recalled pursuant to FDA regulation or other applicable laws or because Midland or Breckenridge, in either of their reasonable discretion determine that a recall is necessary to protect the public health and such recall is due to a Party's breach of its obligations herein, negligence or willful misconduct, then the Party whose conduct caused the need for the recall shall bear all reasonable out-of-pocket costs in connection with the recall, including, but not limited to, all notification letters, postage, phone calls, faxes, courier charges, and all shipping expenses. If the recalled Product are to be destroyed and the recall is due to Midland's breach of its obligations herein, negligence or willful misconduct, Midland, at Breckenridge's request, shall, at Breckenridge's sole discretion, replace free of charge said Product or issue a credit to Breckenridge's account or refund payment to Breckenridge. If such a recall is due to Breckenridge's breach of its obligations herein, negligence or willful misconduct, then Breckenridge shall bear all reasonable out-of-pocket costs in connection with the recall, including, but not limited to, all notification letters and all shipping expenses. The parties agree to cooperate in case of a recall of any of the Product and provide such information as may be necessary to effectuate the recall and to satisfy any regulatory requests about the recall.

(d) Customer Questions and Complaints. Breckenridge shall have the sole responsibility for responding to questions and complaints from Breckenridge's customers relating to the Product. Questions or complaints received by Midland from Breckenridge's customers relating to the Product shall be promptly referred to Breckenridge. Midland shall cooperate as reasonably required to allow Breckenridge to determine the cause of and resolve any Breckenridge questions and complaints. Such assistance shall include follow-up investigations, including testing. In addition, within fourteen (14) days from the date of request, Midland shall provide Breckenridge with all available information that will enable Breckenridge to respond properly to questions or complaints relating to the Product. All reasonable costs incurred by either party in respect of this Section shall be shared equally between the parties after all costs are considered.

SECTION 4. CONTRACTS WITH THIRD PARTIES

4.1 Contracting with Third Parties. Except as specifically provided for in this Agreement, during the term of this Agreement, neither Midland nor Breckenridge shall contract with any third party to develop, or assist in the development of, any [redacted] pharmaceutical product that is equivalent to the Product, without the express written consent of the other party..

4.2 Subcontracting Goods and Services. Upon the prior written consent of Breckenridge, which shall not be unreasonably withheld, Midland may retain or acquire from third parties, including

without limitation Midland's affiliates, goods, services and processes, whether or not patented or patentable, in connection with its work on the Product; provided, further, that any transactions with Midland's affiliates must be on commercially reasonable terms and shall be subject to Breckenridge 's prior approval of price and other terms.

SECTION 5: REPRESENTATIONS AND WARRANTIES

5.1 Representations and Warranties by Midland. Breckenridge is entering into this Agreement in reliance upon the following express representations and warranties, each of which is made by Midland:

(a) Title. The Product is being developed solely by Midland and its authorized agents.

(b) Intellectual Property. Midland warrants that, in developing the Product, it will have performed a diligent search and review of applicable patents and patent applications and will not knowingly infringe upon, misappropriate or use without a valid license any trademark, copyright, trade secret, patent, application, confidential information, intellectual property or contract right of any other person or party. Midland warrants that the Product will not infringe upon any such rights. Midland represents that its execution of this Agreement constitutes verified certification of its non-infringement.

(c) No Conflicts. Midland represents and warrants that neither this Agreement, nor the carrying out of the terms and conditions that are contemplated by this Agreement, will violate the rights of any other party or result in the creation of any right or claim that may adversely affect Midland's performance of its obligations under this Agreement. Midland represents and warrants that no Midland Personnel who will perform any work in connection with the Product is, or is now expected to be, in violation of any term of any employment or consultant contract or agreement, non-disclosure or confidentiality agreement, assignment of inventions agreement, patent disclosure agreement, non-competition agreement, or any other contract or agreement or any restrictive covenant or any other common law obligation to a former or present employer relating to the right of any such employee, consultant or agent to be employed or engaged by Midland in connection with the work to be performed hereunder, and the employment of the Midland Personnel in connection with the research, work or services to be performed hereunder does not and will not subject Breckenridge to any liability thereby.

(d) Freedom to Contract. Midland warrants, represents and covenants that there are no persons, firms, corporations or other legal entities other than Midland having any rights, title or interest in the right to develop the Product or in this Agreement, that Midland has the legal right to enter into this Agreement and perform its obligations hereunder, and that Midland is not aware of any rights of third parties which would prevent it from performing the Services contemplated herein. In addition, the undersigned signatory for Midland represents and warrants that he/she has been duly authorized to sign this Agreement on behalf of Midland and he/she further represents that all requisite corporate and partnership action has been taken on the part of Midland to approve this Agreement.

Midland warrants, represents and covenants that it is a limited liability company duly organized, validly existing and is in good standing under the laws of its applicable jurisdiction, is qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the conduct of its business of the ownership of its properties requires such qualification and has all requisite power and authority, corporate or otherwise, to conduct its business as now being

From: Raman Kapur [ram.kapur@patmedia.net]
Sent: Tuesday, October 09, 2007 11:03 AM
To: llapila@bpirx.com; 'Paul Sudhaker'
Cc: '**Gene Kim'; '**Judi-Lynn Reidinger'; '*Rob Falconer BPI'
Subject: RE: [redacted] Development
Yes.
Paul will communicate with Rob.

From: Larry Lapila [mailto:llapila@breckenridgepharma.com]
Sent: Tuesday, October 09, 2007 11:00 AM
To: 'Raman Kapur'; 'Paul Sudhaker'
Cc: '**Gene Kim'; '**Judi-Lynn Reidinger'; '*Rob Falconer BPI'
Subject: RE: [redacted] Development

So there is stability from a batch made in India?

Thanks

From: Raman Kapur [mailto:ram.kapur@patmedia.net]
Sent: Tuesday, October 09, 2007 10:45 AM
To: ctoffice@breckenridgepharma.com; 'Paul Sudhaker'; 'Larry Lapila'
Cc: '**Gene Kim'; '**Judi-Lynn Reidinger'; '*Rob Falconer BPI'
Subject: RE: [redacted] Development

Larry,

Paul came to New Jersey yesterday and I was able to discuss this with Paul.
According to Paul, the subject of data from the development batch which was done in India did not come up during his discussion with Rob.
Paul will send Rob the Report for that batch. He is traveling today and will be in the air most of today so you can expect this tomorrow.

He is in the final stages of completing the response on the FDA report and has to make some revisions to the schedule for the production of the stability batch
which he will forward to Breckenridge before the end of this week.

The delay is much regretted – I do not know what to say.

Ray

From: CTOffice [mailto:ctoffice@breckenridgepharma.com]
Sent: Monday, October 08, 2007 9:25 AM
To: 'Ray Kapur'; 'Paul Sudhaker'
Cc: '**Gene Kim'; '**Judi-Lynn Reidinger'; '*Rob Falconer BPI'
Subject: RE: [redacted] Development

Midland:

Can we get an update please?

From: Larry J. Lapila [mailto:llapila@breckenridgepharma.com]
Sent: Wednesday, September 26, 2007 8:01 PM
To: Ray Kapur; Paul Sudhaker
Cc: **Gene Kim; **Judi-Lynn Reidinger; *Rob Falconer BPI
Subject: [redacted] Development
Importance: High

Ray / Paul:

We were very disappointed to learn that [redacted] Development is off schedule
We had been advised that the product had stability from a development batch
We learned at our audit that this was not the case and it must now be set up
We also learned that you do not have final methods

Please confirm the status as of today and provide a Revised Time-Line

Also, thank you for the copy of the redacted 483
When can we expect a copy of your response?

Thanks

Larry J. Lapila
Vice President
Business Development

llapila@breckenridgepharma.com

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